

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

No. 12-742V

Filed: June 30, 2016

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SYDNEY RICH, \* UNPUBLISHED

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Petitioner, \* Special Master Hamilton-Fieldman

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v. \* Vaccine Act Entitlement;

\* Causation-in-Fact; Influenza (“Flu”)

SECRETARY OF HEALTH

\* Vaccine; Acute Disseminated

AND HUMAN SERVICES,

\* Encephalomyelitis (“ADEM”).

\*

Respondent. \*

\* \* \* \* \*

Andrew Downing, Van Cott & Talamante, PLLC, Phoenix, AZ, for Petitioner.

Sarah Duncan, United States Department of Justice, Washington, DC, for Respondent.

## DECISION<sup>1</sup>

On November 1, 2012, Sydney Rich (“Petitioner”) filed a petition pursuant to the National Vaccine Injury Compensation Program (“Program”).<sup>2</sup> Petitioner alleged that she developed Acute Disseminated Encephalomyelitis (“ADEM”)<sup>3</sup> because she received the

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<sup>1</sup> Because this decision contains a reasoned explanation for the undersigned’s action in this case, the undersigned intends to post this decision on the website of the United States Court of Federal Claims, in accordance with the purposes espoused in the E-Government Act of 2002. *See* 44 U.S.C. § 3501 (2012). Each party has 14 days to request redaction “of any information furnished by that party: (1) that is a trade secret or commercial or financial in substance and is privileged or confidential; or (2) that includes medical files or similar files, the disclosure of which would constitute a clearly unwarranted invasion of privacy.” Vaccine Rule 18(b).

<sup>2</sup> The National Childhood Vaccine Injury Act of 1986, 42 U.S.C. §§ 300aa-1 to -34 (2012) (“Vaccine Act”), governs the Program.

<sup>3</sup> ADEM is a form of inflammation involving the brain and spinal cord. Encephalomyelitis,

Influenza (“Flu”) Vaccine on September 26, 2010. Pet. at 1, ECF No. 1. Petitioner now moves for judgment on the record, claiming that she has “satisfied her *prima facie* case for entitlement” and therefore deserves compensation. Mot. for J. on the Administrative R. at 8, ECF No. 88 (hereinafter “Mot.”). After reviewing the record, the undersigned disagrees and therefore dismisses the petition.

## I. FACTUAL BACKGROUND

On May 13, 1992, Petitioner was born. Pet’r’s Ex. 1 at 1, ECF No. 5-1. As early as 2004, a physician diagnosed Petitioner with asthma. Pet’r’s Ex. 4, Part 1 at 51, ECF No. 5-4. Although she was prescribed a variety of medications, she did not always take what she was prescribed. *See id.* at 15-16. Petitioner underwent pulmonary testing in 2004, 2006, and 2010, all of which revealed a pulmonary obstruction and low vital capacity. *Id.* at 30, 47-48, 60. Otherwise, Petitioner was healthy and frequently evaluated by her pediatrician, Dr. Colleen Dooley. *See generally id.*

In 2005, 2006, 2007, 2008, and 2009, Petitioner received the Flu vaccine without any reported adverse reactions. *Id.* at 37-38, 42. On September 26, 2010, Petitioner received the Flu vaccine that underscores the instant claim. Order and Ruling on Facts at 10, ECF No. 35.

Roughly two weeks after the vaccination, on October 8, Petitioner visited Dr. Dooley, complaining that it was difficult to breath at night and she had been unable to acquire her asthma medication. Pet’r’s Ex. 4 at 8. She reported using her inhaler ““a lot.”” *Id.* Typically, Heather Rich, Petitioner’s mother, accompanied Petitioner on her medical visits; however, Petitioner’s mother did not attend this visit. *Id.* In the end, Dr. Dooley felt that Petitioner experienced an exacerbation of her asthma, and prescribed her medication and samples. *Id.*

In an affidavit, Petitioner reported that she started to experience fatigue, lethargy, and headaches around this time. Pet’r’s Ex. 1 at 2, ECF No. 5-1. She admitted that she did not tell her mother about these symptoms, explaining that she feared that if she did so, her mother would force her to leave on-campus housing at the University of Oklahoma (where she attended

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acute disseminated, *Dorland’s Illustrated Medical Dictionary* (32nd ed. 2012) (hereinafter “*Dorland’s*”). Usually, an acute viral infection causes ADEM. *Id.* The medical community believes that ADEM is “a manifestation of an autoimmune attack on the myelin of the central nervous system.” *Id.* Symptoms of ADEM “appear rapidly, beginning with encephalitis-like symptoms such as fever, fatigue, headache, nausea, and vomiting,” *id.*; and many patients also experience neurological symptoms, including confusion, blurred vision, weakness, and drowsiness. *Acute Disseminated Encephalomyelitis (ADEM)*, Cleveland Clinic, (Aug. 22, 2014), [http://my.clevelandclinic.org/services/neurological\\_institute/mellen-center-multiple-sclerosis/diseases-conditions/hic-acute-disseminated-encephalomyelitis](http://my.clevelandclinic.org/services/neurological_institute/mellen-center-multiple-sclerosis/diseases-conditions/hic-acute-disseminated-encephalomyelitis).

college), return home, and go to the doctor. *Id.* In addition, she worried that the doctor would prescribe her steroids, which she hoped to avoid due to previous experiences with weight gain. *Id.*

Petitioner's college roommate, Caramia Enrich,<sup>4</sup> filed an affidavit in support of Petitioner's recollection. *See generally* Pet'r's Ex. 3, ECF No. 5-3. Enrich recalled that when Petitioner arrived at college, she was "very vibrant" and "quite healthy"; however, "[a] few weeks after the flu shot," Enrich continued, Petitioner "started showing symptoms of something being wrong," including fatigue, headaches, feelings of heaviness, pain and weakness in her legs, and lethargy. *Id.* at 1-2. Of particular note, Enrich remembered that Petitioner's "symptoms were present before Halloween, 2010, because [Petitioner] had been very excited for the children to come and trick-or-treat in the dorms but was exhausted from the event." *Id.* Enrich recounted that Petitioner's symptoms worsened until Petitioner was hospitalized over winter recess. *Id.* at 2. At the end of her affidavit, she concluded, "[t]here is no question that [Petitioner's] symptoms started in October of 2010, within just a few weeks after she received the flu shot." *Id.*

Aurora Tapia-Contreras,<sup>5</sup> Petitioner's former coworker at Panera Bread, also filed an affidavit in support of this narrative. *See generally* Pet'r's Ex. 24, ECF No. 60-1. Tapia-Contreras recalled, (a) "[b]efore [Petitioner] received her flu shot, [Petitioner] was super healthy," (b) "when [Petitioner] got her flu shot," and (c) Petitioner's "symptoms starting shortly thereafter." *Id.* at 1. Beginning in late October to early November, 2010, Tapia-Contreras observed Petitioner "complaining of headaches" and "experiencing dizziness," remembering that she was "very fatigued" and "not herself." *Id.* In particular, Tapia-Contreras explained that she "was responsible for training [Petitioner] on various tasks" and Petitioner became slow and struggled to perform at work throughout November 2010. *Id.* On multiple occasions, Tapia-Contreras stated, she suggested that Petitioner visit a doctor; however, she indicated that Petitioner stubbornly refused because Petitioner believed that her condition would improve, even though her symptoms worsened. *Id.* In closing, Tapia-Contreras concluded that "[t]here is no question that [Petitioner's] symptoms of headaches, dizziness and brain fog started in October of 2010 and progressively worsened throughout November and December, 2010." *Id.* at 2.

Petitioner's mother, like Petitioner, Enrich, and Tapia-Contreras, also filed an affidavit in support of Petitioner's recollection. *See generally* Pet'r's Ex. 16, ECF No. 23. Petitioner's mother reported that Petitioner began "complaining of fatigue, headaches, and trouble sleeping" a couple of weeks after the vaccination. *Id.* at 1. She also remembered that Petitioner had

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<sup>4</sup> Although Enrich filed her affidavit as "Caramia Testa," she clarified before the Court that she was subsequently married and changed her last name. Tr. at 94-95, ECF No. 66.

<sup>5</sup> While Tapia-Contreras's affidavit lists her name as "Aurora Tapia," the undersigned assumes that the name she provided in the hearing before the Court is the correct one. Tr. at 73.

trouble speaking in complete sentences, was absent from numerous classes, and had recurring headaches. *Id.* at 1-2.

The next documented medical visit (after October 8, 2010) occurred on October 23, 2010, when Petitioner revisited Dr. Dooley, albeit now accompanied by her mother. Pet'r's Ex. 4 at 7. Petitioner repeated her complaints about asthma and an inability to afford her medication. *Id.* As before, Dr. Dooley observed that Petitioner suffered from asthma and prescribed her prednisone and Singulair. *Id.* Notably, the medical records document no complaints of fatigue, heavy legs, difficulty concentrating, or dizziness. *See generally id.*

A little more than two weeks later, on November 10, Petitioner went to the on-campus health center at the University of Oklahoma, complaining of coughing and difficulty breathing. Pet'r's Ex. 15 at 2, ECF No. 20-1. Petitioner reported night sweats, a fever, a sore throat, a headache, an earache, a cough that interfered with her sleep, and muscle aches; that being said, she noted that her symptoms were "somewhat improving." *Id.* Examination revealed wheezing, a red pharynx, mucus, and sinus issues, and a physician diagnosed Petitioner with bronchitis and asthma. *Id.* Petitioner responded positively when the physician administered a nebulizer treatment. *Id.* The treating physician sent her home with additional nebulizer treatments and antibiotics. *Id.*

Like those from the October 28 visit, medical records from the November 10 visit show no symptoms of fatigue, feelings of heaviness, dizziness, difficulty concentrating, or light sensitivity. *See generally id.* But in her affidavit, Petitioner claimed that she visited the on-campus health center because she felt "nauseous," "light headed," "extremely weak," and "like she was going to pass out." Pet'r's Ex. 1 at 2. She also asserted that she informed her mother about her condition, who urged her to come home. *Id.*

After roughly one-and-a-half months, on December 27, Petitioner traveled to the emergency room at Integris Baptist Medical Center because she experienced "wheezing, dyspnea,<sup>[6]</sup> . . . shortness of breath, [and] chest tightness starting yesterday." Pet'r's Ex. 5, Part 1 at 9, ECF No. 6-1. Yet, she explicitly denied suffering from fatigue or night sweats, and a treating physician noted that she was "alert and oriented to person, place, time, and situation," and her neurological exam was normal; although she did report a recent upper respiratory infection. *Id.* at 10, 48-49. A computerized tomography scan showed "extensive right upper lobe pneumonia as well as trace anterior right upper lobe pneumothorax." *Id.* at 46-47. A different lab test ruled out Influenza (types A and B). Pet'r's Ex. 5, Part 9 at 390, ECF No. 6-9. Ultimately, she was admitted to the Intensive Care Unit; diagnosed with community acquired pneumonia in her right upper lobe, a small right pneumothorax, asthma exacerbation, a nodule

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<sup>6</sup> Dyspnea is "breathlessness or shortness of breath," or "difficult or labored respiration." *Dyspnea, Dorland's.*

on her left lower pulmonary lobe, allergic rhinitis, and hypoxemia<sup>7</sup>; and given antibiotics, corticosteroids, and bronchodilators. Pet'r's Ex. 5, Part 1 at 49-50.

The next day, physicians implanted a "Stan French Right Chest Tube" for her pneumothorax. Pet'r's Ex. 5, Part 8 at 374, ECF No. 6-8. After Petitioner continued to experience difficulty breathing, she was intubated. Pet'r's Ex. 5, Part 1 at 41. A subsequent bronchoscopy revealed "severe bronchitis," and physicians initiated tube feeding. *Id.*

Over the next week, her condition worsened. *Id.* MRIs of the brain and cervical spine yielded "extremely abnormal" results, consistent with ADEM, *id.*, as well as "[a]cute infarction of the splenium or the corpus callosum with areas of diffusion restriction, T2 alteration, and abnormal contrast enhancement within the pons, inferior right cerebellar hemisphere, medulla, and cervical spine cord, [which] may relate to hypoxic injury," Pet'r's Ex. 5, Part 8 at 368.

On January 7, 2011, Dr. Aline Brown, an infectious disease specialist, diagnosed Petitioner with ADEM. Pet'r's Ex. 5, Part 4 at 173, ECF No. 6-4. Dr. Brown ordered a sputum test, Pet'r's Ex. 5, Part 1 at 42, which ultimately revealed H1N1 Influenza,<sup>8</sup> Pet'r's Ex. 17 at 3, ECF No. 30-1. As a result, she started Petitioner on a ten-day course of Tamiflu. Pet'r's Ex. 5, Part 1 at 42.

Six days later, on January 13, Petitioner began a four-day course of Intravenous Immunoglobulin treatment. *Id.* When physicians were unable to wean her from her ventilator thereafter, they performed a tracheostomy and a variety of other related treatments over the next few weeks. *Id.* Eventually, by February 9, Petitioner's pneumothorax resolved, and the physicians discontinued her chest tube and ventilator. *Id.* After about a week of additional improvement, Petitioner was transferred to Jim Thorpe Rehabilitation. *Id.*

Evaluating Petitioner's condition in hindsight, two of her treating physicians attributed her hospitalization to H1N1 Influenza. Dr. William B. Schueler, Assistant Professor in the Department of Neurosurgery at the University of Oklahoma Health Sciences Center, noted that Petitioner "unfortunately had some paralysis secondary to the swine flu in January of 2011." Pet'r's Ex. 6 at 24, ECF No. 7-1. Dr. Jenny Le indicated that Petitioner "had an asthma exacerbation in 2010 that turned into bronchitis and then pneumonia," which "in turn was complicated by a 'collapsed lung' which required a chest tube and intubation and ventilator

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<sup>7</sup> Hypoxemia is a deficiency in the "oxygenation of the blood." Hypoxemia, *Dorland's*.

<sup>8</sup> H1N1 Influenza, also known as Swine Flu (because it was initially transmitted by direct contact with pigs), is a type of seasonal flu virus and the source of a 2009 pandemic. *H1N1 Flu Virus (Swine Flu)*, WebMD, <http://www.webmd.com/cold-and-flu/flu-guide/h1n1-flu-virus-swine-flu> (last visited June 26, 2016).

assistance”; as she recovered, “she contracted the ‘swine flu’ . . . which turned into encephalitis.” *Id.* at 27.

Petitioner stayed at Jim Thorpe until she was discharged on March 25, 2011. Pet’r’s Ex. 5, Part 1 at 28. Upon her discharge, physicians diagnosed her with acute demyelinating encephalomalacia with paralysis and quadripareisis, respiratory failure with community-acquired pneumonia, asthma, critical care myopathy,<sup>9</sup> neuropathic pain, a seizure disorder, obesity, atopic dermatitis, a lazy eye, anemia, anxiety, and depression. *Id.*

Following her discharge, Petitioner continued to receive home treatment from health aides. *See generally* Pet’r’s Ex. 6. To this day, Petitioner must use a wheelchair to move about and requires assistance to complete many of the activities of daily life. Pet. at 4, ECF No. 1.

## II. PROCEDURAL HISTORY

After the petition was filed, the case was assigned to Special Master Denise Vowell. *See* Notice of Assignment, ECF No. 2. On March 4, 2013, the case was transferred to the undersigned. *See* Order Reassigning Case, ECF No. 18.

After Petitioner filed medical records and affidavits, the undersigned scheduled a fact-hearing regarding whether Petitioner actually received the alleged vaccine. *See* Order (Apr. 25, 2013) at 1, ECF No. 22. On June 24, 2013, the undersigned conducted that hearing via video conference in Washington, DC. *See* Minute Entry (Apr. 17, 2013). On July 26, 2013, the undersigned concluded that Petitioner “established by preponderant evidence that she received the influenza vaccination at Memorial Christian Church in Oklahoma City, Oklahoma on September 26, 2010.” Order and Ruling on Facts at 10. The undersigned made “no determination of any kind as to whether Petitioner’s alleged damages [were] the result of an adverse reaction to her influenza vaccination.” *Id.*

On September 10, 2013, Respondent filed a Rule 4(c) Report. Rule 4(c) Report, ECF No. 37. Respondent claimed that Petitioner failed to present a *prima facie* case for entitlement under *Althen v. Sec’y of HHS*, 418 F.3d 1274 (Fed. Cir. 2005), as she provided neither a reputable medical theory of causation, evidence of a logical sequence of cause and effect, nor a temporally appropriate relationship between the vaccination and her ADEM. *Id.* at 9-10. As to the latter two points, Respondent identified a dearth of documented neurological symptoms in Petitioner’s medical records prior to her hospitalization for pneumonia and pneumothorax in December 2010.

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<sup>9</sup> Critical care myopathy is a condition featuring “severe muscle weakness, hypotonia, and depressed tendon reflexes of many different muscles,” which “in some may be a complication of therapy with corticosteroids or neuro-muscular blocking agents, but in others the cause is unknown.” Critical Illness Myopathy, *Dorland’s*.

*Id.* at 9-1. Furthermore, Respondent argued, it was more likely that Petitioner's H1N1 infection, not her vaccination, caused her ADEM. *Id.* at 11.

During a September 19, 2013 status conference, the undersigned discussed the case with the parties, who agreed to explore the possibility of settlement while preparing for further litigation. Scheduling Order (Sept. 19, 2013) at 1, ECF No. 38. On December 9, Petitioner filed an expert report from Dr. David Siegler. *See Pet'r's Ex. 18, ECF No. 39-1.* On September 5, 2014, Respondent filed an expert report from Dr. Michael Kohrman. *See Resp't's Ex. A, ECF No. 55-1.*

Of note, both experts agreed that determining the first symptom or manifestation of onset of Petitioner's ADEM was crucial to adjudicating her claim. *See Pet'r's Ex. 18 at 1; Resp't's Ex. A at 10.* Dr. Siegler noted that Petitioner's "3 month interval from vaccine to ADEM admission [was] long" and that he had "not yet found an ADEM case report of a known latency that long." Pet'r's Ex. 18 at 1. Dr. Kohrman, meanwhile, opined that "[n]one of the literature indicates that a three month period between the flu vaccine and the onset of ADEM is a biologically plausible time period to infer causation." Resp't's Ex. A at 10.

During a September 16, 2014 status conference, the parties agreed that a hearing was needed to determine the date of first symptom or manifestation of onset of Petitioner's ADEM. *See Scheduling Order (Sept. 18, 2014), ECF No. 56.* Citing the affidavits from herself, her mother, Enrich, and Tapia-Contreras, Petitioner alleged that her first symptoms arose "within weeks of receiving the influenza vaccination on September 26, 2010." Pet'r's Prehearing Submissions at 6, ECF No. 61. Citing Petitioner's medical records, Respondent countered that Petitioner's symptoms did not arise until at least December 27, 2010, when she was hospitalized for pneumonia and pneumothorax, and when she first reported neurological complaints. Resp't's Rule 4(c) Report at 9-10.

On October 30, 2014, the undersigned presided over an onset hearing in Oklahoma City, Oklahoma. *See Minute Entry (Nov. 3, 2014).* Petitioner, her mother, Enrich, and Tapia-Contreras, all testified at the hearing, largely reiterating the attestations in their affidavits. *See generally Tr.*

Despite their testimony, the undersigned concluded that Petitioner's first symptom or manifestation of onset of ADEM "began concurrently with or shortly after Petitioner's hospitalization for pneumonia, pneumothorax, and hypoxemia, on or after December 27, 2010." *Rich v. Sec'y of HHS*, No. 12-742V, 2015 U.S. Claims LEXIS 1288, at \*36 (Fed. Cl. Spec. Mstr. Sep. 16, 2015). The undersigned found that Petitioner's medical records did not support the affiants' testimony that Petitioner began to experience symptoms of ADEM in late October to early November. *Id.* at \*34. The undersigned observed that Petitioner visited physicians on

three occasions, beginning in mid-October, before she eventually entered the emergency room on December 27, 2010; but none of the medical records from these visits note the symptoms of ADEM that the affiants would later describe. *Id.* at \*32-33. Moreover, the undersigned noted, at the November 10 visit to the on-campus health clinic, “Petitioner had three separate opportunities to tell someone at the clinic about these symptoms: when she filled out the intake sheet, when she spoke with the doctor, and when she spoke with the nurse after the first nebulizer treatment, but she did not avail herself of those opportunities.” *Id.* at \*34. Instead, the undersigned explained, that visit, like those before it, exclusively focused on “her difficulty breathing and related issues.” *Id.* at \*34.

The undersigned rejected Petitioner’s suggestion that, even though she experienced symptoms of ADEM, she omitted mention of them during these three visits:

Petitioner was familiar with doctors, as she had had asthma, a chronic illness, since childhood and would go to the doctor occasionally for a flare-up of asthma or to refill an asthma related medication prescription. Therefore, she was familiar with the practice of visiting a physician and reporting symptoms, particularly when prompted. She continued this practice when she went to college: she went to the doctor three times that first semester, and she reported the symptoms from which she was suffering so that they could be treated. The undersigned is not persuaded that Petitioner would not be forthcoming with her doctors, particularly if the symptoms were as unprecedented, persistent and severe as has been described. The undersigned finds that Petitioner reported the symptoms she was experiencing, related to the severe pulmonary illness for which she was eventually hospitalized.

*Id.* at 34-35 (citation omitted). After the undersigned’s finding of fact, the undersigned offered Petitioner an opportunity to submit a supplemental expert report. Scheduling Order (Nov. 6, 2015), ECF No. 84.

In response, Petitioner submitted a letter from Dr. Siegler. Letter from pediatric neurologist, Dr. David Siegler, ECF No. 85-1. While maintaining that Petitioner’s claim of “flu vaccine-induced ADEM is medically plausible,” Dr. Siegler explained, his theory “linking her flu vaccine with her ultimate diagnosis of ADEM is dependent on the oral history of multiple neurologic symptoms developing a few weeks post-vaccine and persisting through her admission to Baptist Hospital in December 2010.” *Id.* Because the undersigned’s aforementioned finding of fact forecloses this “oral history,” Dr. Siegler continued, it “prevents [him] offering an opinion on causation in [Petitioner’s] claim.” *Id.*

Petitioner now moves for judgment on the record. *See generally* Mot. While positing in her motion that she “satisfied her *prima facie* case for entitlement,” Petitioner offers no specific argument in favor of causation; rather, she spends virtually the entire brief challenging the undersigned’s finding of fact. *Id.* at 3-9.

Respondent counters that Petitioner has established neither “a proximate temporal relationship between the vaccination and her injury” nor “a logical sequence of cause and effect showing that the vaccination was the reason for her injury.” Resp. to Mot. for J. on the Administrative R. at 16, 22, ECF No. 90 (hereinafter “Resp.”). As to the former, Respondent points out that both parties’ experts agreed that there is no evidence to suggest that it is biologically possible for a latency period of three months to separate vaccination and the onset of ADEM; and here, given the undersigned’s finding of fact, the parties are faced with just such a latency period. *Id.* at 21. Regarding the latter, Respondent emphasizes that Petitioner never addressed the possibility of H1N1 as an alternative cause of her ADEM, despite records from at least two treating physicians linking H1N1 and her ADEM. *Id.* at 22-23. Accordingly, Respondent argues, Petitioner is not entitled to compensation under the Program and her claim ought to be dismissed.

### III. LEGAL STANDARD

To receive compensation under the Vaccine Act, a petitioner must demonstrate either that (1) she suffered a “Table injury,” that is, she received a vaccine and developed an injury in the manner specified by the Vaccine Injury Table, *see* 42 U.S.C. § 300aa-14 (2012); or (2) she suffered an injury that was in-fact caused by her receipt of a vaccine covered by the Act, *see* 42 U.S.C. § 300aa-11(c)(1)(C) (2012). When, as here, the petitioner does not allege a Table injury, she must prove the latter by a preponderance of the evidence. *Althen v. Sec’y of HHS*, 418 F.3d 1274, 1278 (Fed. Cir. 2005).

The Federal Circuit has set forth a three-pronged inquiry to determine when the petitioner has established a causal link between a vaccine and an injury. *Id.* at 1278. Under *Althen*, the petitioner must provide: “(1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.” *Id.*

Under the first prong, the petitioner’s theory must show that the vaccine received *can* cause the alleged injury. *Pafford v. Sec’y of HHS*, 451 F.3d 1352, 1356 (Fed. Cir. 2006) (internal quotation marks omitted). The medical theory set forth by the petitioner need only be “legally probable, not medically or scientifically certain.” *Knudsen v. Sec’y of HHS*, 35 F.3d 543, 548-49 (Fed. Cir. 1994). If the petitioner proffers a medical opinion to support the theory alleged, the

basis for the opinion and the reliability of that basis must be considered in determining how much weight to afford the offered opinion. *Broekelschen v. Sec'y of HHS*, 618 F.3d 1339, 1347 (Fed. Cir. 2010).

To satisfy *Althen*'s second prong, the petitioner must prove that the vaccine received *did* cause the alleged injury. *Capizzano v. Sec'y of HHS*, 440 F.3d 1317, 1326 (Fed. Cir. 2006). The petitioner may satisfy her burden by presenting circumstantial evidence, and reliable medical opinions from experts, as well as treating physicians; she is not required to offer "epidemiologic studies, rechallenge, the presence of pathological markers or genetic disposition, or general acceptance in the scientific or medical communities to establish a logical sequence of cause and effect." *Id.* at 1325-26. Ultimately, the "logical sequence of cause and effect must be informed by sound and reliable medical or scientific explanation." *Knudsen*, 35 F.3d at 548 (internal quotation marks omitted).

As to *Althen*'s third prong, it helps to establish the connection between the causal theory of the first prong and the more fact-based cause and effect arguments of the second. *De Bazan v. Sec'y of HHS*, 539 F.3d 1347, 1352 (Fed. Cir. 2008). In short, the petitioner must demonstrate "that the onset of symptoms occurred within a timeframe for which, given the medical understanding of the disorder's etiology, it is medically acceptable to infer causation-in-fact." *Id.*

If the petitioner satisfies all three prongs by a preponderance of the evidence, she establishes a *prima facie* case entitling her to compensation. *Walther v. Sec'y of HHS*, 485 F.3d 1146, 1149 (Fed. Cir. 2007). At that point, the burden shifts to Respondent to prove (by a preponderance of the evidence) that factors unrelated to the administration of the vaccine *actually caused* the alleged injury. *Walther*, 485 F.3d at 1151. Stated differently: if, after presenting a *prima facie* case, "the evidence is seen in equipoise, then the government has failed in its burden of persuasion and compensation must be awarded." *Knudsen*, 35 F.3d at 550.

#### IV. ANALYSIS

After reviewing the record, the undersigned concludes that Petitioner has failed to present a *prima facie* case entitling her to compensation. Specifically, Petitioner has not made the necessary showings under *Althen*'s second or third prongs.<sup>10</sup> In both his initial and supplemental expert reports, Dr. Siegler affirmed that he knew of no credible medical evidence to suggest that a three-month latency period between a vaccination and the onset of ADEM is consistent with causation, and Dr. Kohrmann concurred. Furthermore, as Respondent aptly notes, at least two of Petitioner's treating physicians ascribed her ADEM to her H1N1, not the vaccination. In sum,

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<sup>10</sup> The undersigned makes no finding as to *Althen*'s first prong.

Petitioner has not demonstrated, by a preponderance of the evidence, that the vaccination caused her injury.<sup>11</sup>

#### V. CONCLUSION

For these reasons, the undersigned concludes that Petitioner is not entitled to compensation under the Program. Therefore, the petition is **DISMISSED**.

In the absence of a motion for review filed pursuant to RCFC Appendix B, the Clerk of the Court is directed to enter judgment herewith.<sup>12</sup>

/s/ Lisa D. Hamilton-Fieldman

Lisa D. Hamilton-Fieldman

Special Master

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<sup>11</sup> To the extent Petitioner's brief is an invitation for the undersigned to reconsider her finding of fact, the undersigned declines the invitation. The undersigned remains convinced that Petitioner's contemporaneous medical records, documenting three separate visits, present a more accurate picture of Petitioner's medical history than the recollections of Petitioner, her mother, and her friends.

<sup>12</sup> Pursuant to Vaccine Rule 11(a), the parties can expedite entry of judgment by filing a notice renouncing the right to seek review by a United States Court of Federal Claims judge.